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(54) **Low velocity aortic cannula**

Aortakanüle mit niedriger Ausströmgeschwindigkeit

Canule aortique présentant une faible vitesse d'écoulement

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US-A- 4 643 712 **US-A- 4 801 297**

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Description

[0001] This invention relates to a low velocity aortic cannula for use during hear surgery, and a method of delivering blood to the aorta using a low velocity aortic cannula.

[0002] Aortic cannulas are used to return blood to the aorta while the heart is by-passed during heart surgery. These cannulas are purposely made with small diameters (typically six to eight millimeters, but even smaller for pediatric applications) to minimize the disruption to the aorta, which in many heart surgery patients have advanced complex atherosclerotic lesions with adherent blood thrombi. The flow velocities through these small diameter cannula must be very high in order to maintain a satisfactory blood flow rate of about five to seven liters per minute. In at least some styles of conventional aortic cannula now in use, this high velocity resulted in "jet" flow emanating from the distal end of the cannula, which acted as a nozzle. It is believed that the force of this narrow jet stream may dislodge atheromatous material from the walls of the aorta, causing embolisms. As surgical equipment and techniques improve, making heart surgery available to older and more seriously ill patients, thrombo-athercembolisms affect an increasing number of patients due to the increasing extent of atherosclerosis with age.

[0003] The size of aortic cannula is constrained by the constricted size of the aorta of the typical heart surgery patient. Moreover, the ability to diffuse flow is restricted by the fragility of the blood, which is easily damaged by the shear stresses associated with turbulence.

[0004] US-A-4 643 712 discloses an aortic cannula for insertion into the aorta during heart surgery to provide blood to the aorta. The cannula comprises a head shaped as an oblate cone that flares out from the front end toward the base, the front head end being an ellipse in cross-section, while the head base is essentially a circle carrying a blood flow divider, the flow of blood passing along a tube provided with a slidable sleeve and having at least two through holes made in its walls immediately at the head base. The cannula construction is intended to rule out the danger of inflicting traumatic lesion upon the aortic tissues and the loss of blood resulting from insertion of the head of the cannula into the aorta, reduce the turbulence or the blood flow supplied, and preclude the risk of air bubbles penetrating into the patient's blood.

[0005] The aortic cannulas of the present invention are characterized by the features of the claims, and are adapted to provide high volume flow at relatively lower flow velocities than the conventional aortic cannulas presently available, thereby reducing the jet flow and consequently reducing the incidence of thrombo-atheroembolisms. Generally aortic cannulas constructed according to the principles of this invention comprise a diffuser that blocks some or all of the flow through the distal end of the cannula, and a plurality of outlet open-

ings in the sidewall of cannula adjacent the distal end to maintain flow volume.

[0006] According to an embodiment of this invention, the distal end of the aortic cannula is partially blocked by a diffuser having helical splines. There are a plurality of openings in the sidewall of the cannula between the splines on the diffuser to permit blood to flow out of the cannula. Additional outlet openings can be provided in the sidewall of the cannula upstream of the diffuser to reduce back pressure and the flow velocity from the distal end of the cannula.

[0007] The outlet openings provide for increased flow, thereby reducing the flow velocity from the cannula. The openings allow the flow to quickly establish a stable, more uniform velocity flow. The diffuser diverts the flow out of the outlet openings, minimizing hemolysis or other damage to the blood, reduces the flow through distal end of the cannula, preventing jetting, and diverts a portion of the flow through the outlet openings in the sidewall surrounding the diffuser. Thus, the aortic cannula of the present invention reduces the high velocity jetting that can occur with some conventional aortic cannulas, while maintaining flow rate and minimizing damage to the blood.

[0008] These and other features and advantages will be in part apparent and in part pointed out hereinafter. It should be noted that Figs. 1-12 illustrate features of the invention but do not show an embodiment of the invention as claimed in claim 1.

Fig. 1 is a side elevation view of an aortic cannula;
Fig. 2 is a right side elevation view of the tip of the aortic cannula;

Fig. 3 is a left side elevation view of the tip of the aortic cannula;

Fig. 4 is a top plan view of the tip of the aortic cannula;

Fig. 5 is a longitudinal cross-sectional view of the tip of the aortic cannula, taken along the plane of line 5-5 in Fig. 4;

Fig. 6 is a transverse cross-sectional view of the tip of the aortic cannula, taken along the plane of line 6-6 in Fig. 4;

Fig. 7 is a side elevation view of a first alternate construction of an aortic cannula;

Fig. 8 is a transverse cross-sectional view of the first alternate construction of an aortic cannula, taken along the plane of line 8-8 in Fig. 7;

Fig. 9 is a side elevation view of a second alternate construction of an aortic cannula;

Fig. 10 is a transverse cross-sectional view of the second alternate construction, taken along the plane of line 10-10 in Fig. 9;

Fig. 11 is a partial side view of a third alternate construction, showing an alternate configuration for the cap;

Fig. 12 is a partial side view of a fourth alternate construction, showing an alternate configuration for

the cap;

Fig. 13 is an enlarged perspective view of an embodiment of an aortic cannula constructed according to the principles of this invention;

Fig. 14 is an enlarged perspective view of the tip of the aortic cannula of the embodiment, with the helical diffuser removed;

Fig. 15 is an end elevation view of the tip of the aortic cannula of the embodiment;

Fig. 16 is a right side elevation view of the tip of the aortic cannula of the embodiment;

Fig. 17 is a left side elevation view of the tip of the aortic cannula of the embodiment;

Fig. 18 is a top plan view of the tip of the aortic cannula of the embodiment taken along the plane of line 18-18 in Fig. 16;

Fig. 19 is an end elevation of the diffuser employed in the embodiment;

Fig. 20 is side elevation of the diffuser employed in the embodiment;

Fig. 21 is an end elevation view of an alternate construction of the diffuser employed in the embodiment;

Fig. 22 is a side elevation view of the alternate construction of the diffuser employed in the embodiment;

Fig. 23 is a side elevation view of alternate construction of the aortic cannula of the embodiment;

Fig. 24 is a side elevation view of the alternative construction shown in Fig. 23, rotated axially 90°;

Fig. 25 is a side elevation view of the alternative construction shown in Fig. 23, rotated axially 180°;

Fig. 26 is a graph showing the flow velocities created across the diameter of an aorta by a conventional aortic cannula, by an aortic cannula as shown in Figs. 1-12, and by the aortic cannula of the invention, at a distance of 12 mm from the tip of the cannula; and

Fig. 27 is a chart showing the comparative forces generated by the flows from two styles of conventional aortic cannulas, from an aortic cannula as shown in Figs. 1-12, and from the aortic cannula of the invention.

[0009] Corresponding reference numerals indicate corresponding parts throughout the several views of the drawings.

[0010] An aortic cannula is indicated generally as 20 in Fig. 1. The coronary cannula 20 comprises a generally tubular sidewall 22 having a proximal end 24 and a distal end 26, with a lumen 28 extending therebetween. As shown in Fig. 1, the cannula tapers toward the distal end so that the distal end has a diameter of between about 6 mm and 8 mm, to fit in the aorta of the patient. As shown in Fig. 2, the distal end 26 of the cannula 20 is closed with an end cap 30. The cap 30 may have a rounded, hemispherical shape, as shown in Figs. 1-10, to facilitate the insertion of the distal end 26 of the can-

nula 20 into the aorta. The cap may also have a more conical configuration as shown in Fig. 11, or a rounded beveled configuration resembling a conventional aortic cannula tip, as shown in Fig. 12. The rounded shape of the tip also reduces the likelihood of damage to the aorta once the distal end 26 of the cannula 20 is placed in the aorta. The cap 30 and the diffuser (described below) are preferably molded in one piece with the cannula.

[0011] A tapering diffuser 32 extends from the end cap 30, inside the lumen 28 toward the proximal end 24 of the cannula 20. The diffuser 32 tapers toward the proximal end, i.e., in the upstream direction. The diffuser 32 preferably has a conical configuration, and is most preferably frustoconical, with a blunt, rounded apex so that the diffuser does not damage the blood flowing past it. The conical diffuser preferably has an apex angle of between about 20° and about 40° to smoothly diffuse the flow and impart a radially outward component to the flow. The diffuser 32 could also be pyramidal (or frustopyramidal), with a face of the pyramid oriented toward each of the outlet openings (described below).

[0012] A plurality of outlet openings 34 are formed in the sidewall of the cannula 20, adjacent the distal end 26. These openings 34 preferably have an arched configuration, with the curved portion 36 of each arch oriented toward the proximal end 24, i.e., oriented in the upstream direction. There are preferably six openings 34, equally spaced around the circumference of the distal end 26 of the cannula 20 (Figs. 2-6). However, there could be three (Figs. 7 and 8) or four (Figs. 9 and 10) or some other suitable number of openings 34. The total area of the openings 34 is preferably greater than the area of the distal end opening in a conventional aortic cannula of the same diameter. The length of the openings 34 is preferably slightly greater than the length of the diffuser 32, so that the openings extend further upstream on the sidewall 22 than the diffuser projects in the lumen 28. Thus, the cross-sectional area of the lumen 28 taken up by the diffuser 32 is made up by the openings 34 so that in effect the diffuser causes no decrease in the cross-sectional area available for flow. Thus the diffuser does not interfere with flow or deleteriously increase back pressure; the diffuser merely redirects the flow.

[0013] As blood flows through the cannula 20 and reaches the distal end 26, the diffuser 32 imparts a radially outward component to the flow. The diffused flow is thus urged out through the openings 34, with a reduced velocity, because of the greater area of the openings 34, and a generally diffused state because of the diffuser 32 and the radially outward orientation of the openings 34. The smooth, continuous shape of the diffuser 32, the blunt, rounded configuration of the end of the diffuser, and the rounded configuration of the openings 34 all help to reduce turbulence in the blood flow and reduce hemolysis. The corners and edges in the cannula 20 are preferably rounded to minimize turbulence, and promote

a smooth, diffused flow while minimizing the increase in back pressure.

[0014] Deflectors 38 can be formed at the base 40 of each of the openings 34, opposite from the arched portions 36 of the openings. The deflectors 38 are preferably in the form of indentations in the cap 30 which further deflect the diffused flow radially outwardly. The deflectors have the shape of a portion of a sphere. The deflectors 38 splay out the flow, forming an "umbrella" pattern that establishes a stable flow in the aorta, reducing high velocity jetting and evening the flow velocity across the diameter of the aorta.

[0015] An embodiment of an aortic cannula constructed according to the principles of this invention is indicated generally as 20' in Figs. 13-18. The cannula 20' is similar to cannula 20, and corresponding reference numerals indicate corresponding parts throughout the several views of the drawings. The aortic cannula 20' comprises a sidewall 22, with a proximal end 24 and a distal end 26', and a lumen 28 extending therebetween. As shown in Figs. 13-18, the distal end 26' of the cannula 20' has a diffuser 100 therein. The diffuser 100 has a helical configuration, as shown best in Figs. 18 and 20. The diffuser 100 functions to slow the flow through the distal end 26' of the cannula 20', and to diffuse the direction of the flow. The diffuser 100 can be held in place by the tapering configuration of the distal end of the cannula 20', by adhesives, by ultrasonic welding, or by some other suitable means.

[0016] The sidewall of the cannula 20' surrounding the diffuser 100 has a plurality of outlet openings 102 therein to permit flow of blood from the cannula. The outlet openings 102 prevent a large back pressure from developing because of the diffuser 100 which partially blocks the outlet of the cannula. The outlet openings 102 also help maintain a satisfactory flow rate from the cannula. It is desirable that the openings be as large as possible, yet still fit between the splines on the diffuser, so that the openings do not form jets and to minimize hemolysis.

[0017] The diffuser 100 is preferably formed from a flat rectangular member with a single 180° twist therein, to give the diffuser a generally helical configuration. The diffuser 100 thus has two oppositely facing splines, formed by the edges of the member. However, in an alternative construction of the diffuser 100', shown in Figs. 21 and 22, the diffuser has a more complex helical shape, with more splines. However, the greater the number of splines the smaller the openings 102 must be to fit between the splines. Additional outlet openings 104 may be provided upstream of the openings 102 to further reduce the back pressure and increase the flow.

[0018] An alternate construction of the distal end 26" of the cannula 20' of the embodiment is shown on Figs. 23-25. The distal end 26" has a blunt, rounded configuration. There is a helical diffuser 100 inside the distal end 26". Rather than circular outlet openings 102, the distal end has arcuate slots 106 and 108 extending

diagonally through the sidewall of the cannula, on opposite sides. The concave shape of slot 106 faces distally, the concave shape of slot 108 faces proximal.

OPERATION

[0019] In operation, an opening is made into the aorta and the distal end of the cannula 20 or 20' is inserted into the aorta. The rounded configuration of cap 30 facilitates the insertion of cannula 20 into the aorta. The beveled configuration of the distal end of cannula 20' facilitates the insertion of the cannula in to the aorta. When the cannula 20 or 20' is secured in place, blood flow is initiated. Blood flows through the lumen 28 and out the distal end 26 of the cannula.

[0020] In cannula 20, the blood encounters the blunt conical diffuser 32 which, by virtue of its low cone angle, gently redirects the flow radially outwardly, through the openings 34. Thus, rather than a jetting, axial flow experienced with conventional aortic cannula, the cannula 20 provides a diffused flow that more quickly establishes a stable, more uniform velocity blood flow in the aorta. The cannula 20 preferably has deflectors 38 at the base of the openings that further deflect the flow radially outwardly. The flow properties of the blood are such that the deflectors create an "umbrella" flow pattern that more quickly establishes a uniform flow in the aorta.

[0021] In cannula 20' the diffuser 100 slows flow through the axial opening in the distal end of the cannula, forcing flow radially outwardly through the outlet openings 102 and 104. Thus the axial jetting is eliminated and blood fills the aorta through the openings 102 and 104 in the sidewall 22.

[0022] The flow velocity reduction achieved by the cannula of this invention is illustrated in Fig. 26, which shows the flow velocities across the diameter of the aorta, measured 12 mm from the tip of a conventional aortic cannula, 12 mm from the tip of an aortic cannula 20, and 12 mm from the tip of an aortic cannula 20' of the invention. Fig. 26 shows that the flow velocities generated by a conventional cannula 12 mm from the tip are as high as 200 cm/sec, and vary considerably across the diameter of the aorta. However, with the cannula 20, the maximum flow velocity 12 mm from the tip is about 130 cm/sec, and the variation in the velocity across the diameter of the aorta is significantly reduced. Similarly, with the cannula 20' of the invention, the maximum flow velocity 12 mm from the tip is about 100 cm/sec, and the variation in the velocity across the diameter of the aorta is also significantly reduced.

[0023] Fig. 27 illustrates the reduction in flow force achieved by the cannulas 20 and 20'. Fig. 27 shows the flow force measured 12 mm from the tip of two conventional cannulas as about 0.072 kg (0.16 pounds) and 0.05 kg (0.11 pounds), respectively. However the flow force measured 12 mm from the tip of cannula 0.014 kg (0.03 pounds), as is the flow force measured 12 mm

from the tip of cannula 20'.

[0024] The cannula 20' of this invention thus reduces the maximum flow velocity, the variation in flow velocity, and the maximum flow force, while maintaining the overall flow rate. These reductions are believed to be significant in the reduction of thrombo-atheroembolisms, and other possible complications of heart surgery.

[0025] As various changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

Claims

1. An aortic cannula (20) for insertion into the aorta during heart surgery to provide blood to the aorta, the cannula comprising a sidewall (22) having a proximal end (24) and a distal end (26) and a lumen (28) therethrough, a diffuser (100; 100') inside the lumen adjacent the distal end, the diffuser having a plurality of helical splines thereon, and outlet openings (102) in the portion of the sidewall of the cannula surrounding the diffuser, between the splines on the diffuser.
2. The aortic cannula according to claim 1 wherein the diffuser (100; 100') at least partially blocks the distal opening of the lumen.
3. The aortic cannula according to claim 1 or 2 further comprising a cap (30) for blocking axial flow from the distal end of the cannula, and wherein the diffuser extends generally upstream in the lumen toward the proximal end of the cannula, and tapers in the upstream direction and wherein there are at least two outlet openings (102, 104) in the sidewall of the cannula.
4. The aortic cannula according to any of claims 1 to 3 wherein the diffuser (32; 100) has a generally conical shape, with a blunt tip.
5. The aortic cannula according to any of claims 1 to 4 wherein the outlet openings (34; 102, 104) comprise (106, 108) in the sidewall of the cannula, adjacent the distal end.
6. The aortic cannula according to claim 5 wherein the proximal ends of the slots are rounded.
7. The aortic cannula according to claim 5 or 6 wherein the slots extend proximally beyond the proximal end of the diffuser.
8. The aortic cannula according to any of claims 1 to 7 wherein there are three, four or six outlet openings

(34; 102, 104) in the sidewall.

9. The aortic cannula according to any of claims 1 to 8 further comprising a deflector (38) at the base (40) of each outlet opening (34) for deflecting at least a portion of the flow from each opening radially outwardly.
10. The aortic cannula according to any of claims 3 to 9 wherein the deflector comprises an indentation in the cap.
11. The aortic cannula according to claim 10 wherein the indentation has the shape of a portion of a sphere.
12. The aortic cannula according to any of claims 1 to 11 wherein the openings are generally circular.
13. The aortic cannula according to any of claims 3 to 12 wherein the distal end of the cap (30) has a rounded, hemispherical shape.
14. The aortic cannula according to any of claims 3 to 12 wherein the distal end of the cap (30a) has a rounded, conical shape.
15. The aortic cannula according to any of claims 3 to 12 wherein the distal end of the cap (30b) has a rounded, beveled shape.
16. The aortic cannula according to any of claims 1 to 15 for use in a method of providing blood to the aorta of a patient.

Patentansprüche

1. Aortenkanüle (20') zum Einführen in die Aorta bei der Herzchirurgie, um Blut zur Aorta zu führen, wobei die Kanüle aufweist: eine Seitenwand (22) mit einem proximalen Ende (24) und einem distalen Ende (26') und einem sich dazwischen erstreckenden Lumen (28), einen Diffusor (100; 100') innerhalb des Lumens benachbart zum distalen Ende, wobei am Diffusor mehrere Schraubenkeile vorhanden sind, und Auslaßöffnungen (102) im den Diffusor umgebenden Abschnitt der Seitenwand der Kanüle zwischen den Keilen am Diffusor.
2. Aortenkanüle nach Anspruch 1, wobei der Diffusor (100; 100') die distale Öffnung des Lumens mindestens teilweise blockiert.
3. Aortenkanüle nach Anspruch 1 oder 2 mit einer Kappe (30) zum Blockieren des Axialflusses aus dem distalen Ende der Kanüle, wobei sich der Diffusor allgemein stromaufwärts im Lumen zum proximalen Ende der Kanüle erstreckt und sich in

Stromaufwärtsrichtung verjüngt, und wobei mindestens zwei Auslaßöffnungen (102, 104) in der Seitenwand der Kanüle vorhanden sind.

4. Aortenkanüle nach einem der Ansprüche 1 bis 3, wobei der Diffusor (32; 100) eine allgemein konische Form mit einer stumpfen Spitze hat. 5
5. Aortenkanüle nach einem der Ansprüche 1 bis 4, wobei die Auslaßöffnungen (34; 102, 104) Schlitz- 10
(106, 108) in der Seitenwand der Kanüle benachbart zum distalen Ende aufweisen.
6. Aortenkanüle nach Anspruch 5, wobei die proximalen Enden der Schlitz- 15
abgerundet sind.
7. Aortenkanüle nach Anspruch 5 oder 6, wobei sich die Schlitz- 20
proximal über das proximale Ende des Diffusors hinaus erstrecken.
8. Aortenkanüle nach einem der Ansprüche 1 bis 7, wobei drei, vier oder sechs Auslaßöffnungen (34; 102, 104) in der Seitenwand vorhanden sind. 25
9. Aortenkanüle nach einem der Ansprüche 1 bis 8 mit einem Deflektor (38) an der Basis (40) jeder Auslaßöffnung (34) zum Ablenken mindestens eines Teils des Flusses aus jeder Öffnung radial nach außen. 30
10. Aortenkanüle nach einem der Ansprüche 3 bis 9, wobei der Deflektor eine Vertiefung in der Kappe aufweist. 35
11. Aortenkanüle nach Anspruch 10, wobei die Vertiefung die Form eines Abschnitts einer Kugel hat. 40
12. Aortenkanüle nach einem der Ansprüche 1 bis 11, wobei die Öffnungen allgemein kreisförmig sind. 45
13. Aortenkanüle nach einem der Ansprüche 3 bis 12, wobei das distale Ende der Kappe (30) eine abgerundete Halbkugelform hat. 50
14. Aortenkanüle nach einem der Ansprüche 3 bis 12, wobei das distale Ende der Kappe (30a) eine abgerundete, konische Form hat. 55
15. Aortenkanüle nach einem der Ansprüche 3 bis 12, wobei das distale Ende der Kappe (30b) eine abgerundete, abgeschrägte Form hat.
16. Aortenkanüle nach einem der Ansprüche 1 bis 15 zur Verwendung in einem Verfahren zum Zuführen von Blut zur Aorta eines Patienten.

Revendications

1. Canule aortique (20) destinée à être insérée dans l'aorte au cours d'une intervention de chirurgie cardiaque afin de délivrer du sang dans l'aorte, la canule comprenant une paroi latérale (22) ayant une extrémité proximale (24) et une extrémité distale (26) et une lumière (28) disposée à travers celle-ci, un diffuseur (100 ; 100') situé à l'intérieur de la lumière de manière adjacente à l'extrémité distale, le diffuseur présentant une pluralité de cannelures hélicoïdales ménagées sur celui-ci, et des ouvertures d'évacuation (102) dans la partie de la paroi latérale de la canule entourant le diffuseur entre les cannelures ménagées sur le diffuseur.
2. Canule aortique selon la revendication 1, dans laquelle le diffuseur (100 ; 100') bloque au moins partiellement l'ouverture distale de la lumière.
3. Canule aortique selon la revendication 1 ou 2, comprenant en outre une calotte (30) destinée à bloquer l'écoulement axial depuis l'extrémité distale de la canule, et dans laquelle le diffuseur s'étend globalement en amont dans la lumière vers l'extrémité proximale de la canule, et s'effile dans la direction amont et dans laquelle il existe au moins deux ouvertures d'évacuation (102 ; 104) dans la paroi latérale de la canule.
4. Canule aortique selon l'une quelconque des revendications 1 à 3, dans laquelle le diffuseur (32 ; 100) a une forme globalement conique avec une pointe émoussée.
5. Canule aortique selon l'une quelconque des revendications 1 à 4, dans laquelle les ouvertures d'évacuation (34 ; 102, 104) comprennent des fentes (106, 108) dans la paroi latérale de la canule, de manière adjacente à l'extrémité distale.
6. Canule selon la revendication 5, dans laquelle les extrémités proximales des fentes sont arrondies.
7. Canule aortique selon la revendication 5 ou 6, dans laquelle les fentes s'étendent de manière proximale au-delà de l'extrémité proximale du diffuseur.
8. Canule aortique selon l'une quelconque des revendications 1 à 7, dans lequel il existe trois, quatre ou six ouvertures d'évacuation (34 ; 102, 104) dans la paroi latérale.
9. Canule aortique selon l'une quelconque des revendications 1 à 8, comprenant en outre un déflecteur (38) à la base (40) de chaque ouverture d'évacuation (34) destiné à dévier, radialement vers l'extérieur, au moins une partie de l'écoulement issu de

chaque ouverture.

10. Canule aortique selon l'une quelconque des revendications 3 à 9, dans laquelle le déflecteur comprend une échancrure dans la calotte. 5
11. Canule aortique selon la revendication 10, dans laquelle l'échancrure se présente sous la forme d'une partie de sphère. 10
12. Canule aortique selon l'une quelconque des revendications 1 à 11, dans laquelle les ouvertures sont globalement circulaires.
13. Canule aortique selon l'une quelconque des revendications 3 à 12, dans laquelle l'extrémité distale de la calotte (30) présente une forme arrondie hémisphérique. 15
14. Canule aortique selon l'une quelconque des revendications 3 à 12, dans laquelle l'extrémité distale de la calotte (30a) présente une forme arrondie conique. 20
15. Canule aortique selon l'une quelconque des revendications 3 à 12, dans laquelle l'extrémité distale de la calotte (30b) a une extrémité arrondie biseautée. 25
16. Canule aortique selon l'une quelconque des revendications 1 à 15, destinée à être utilisée dans un procédé constituant à délivrer du sang dans l'aorte d'un patient. 30

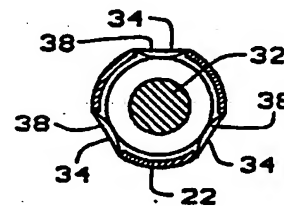
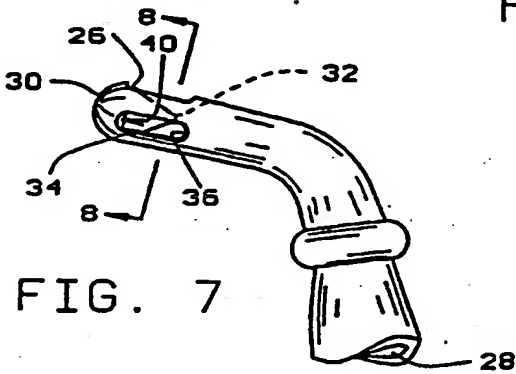
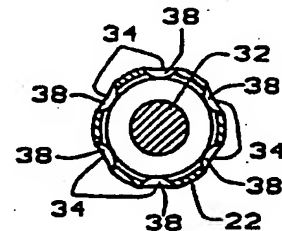
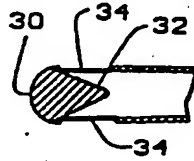
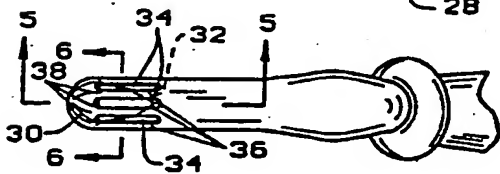
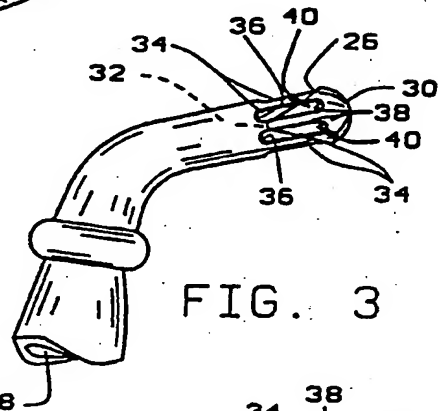
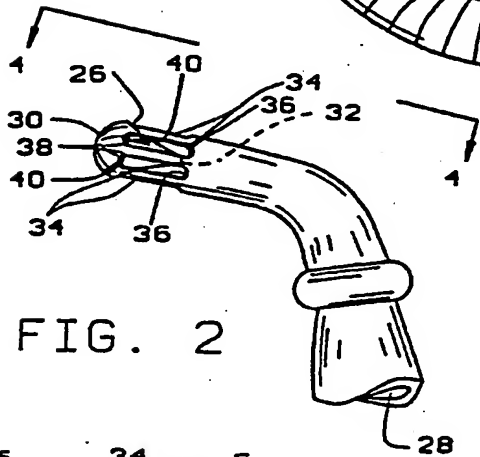
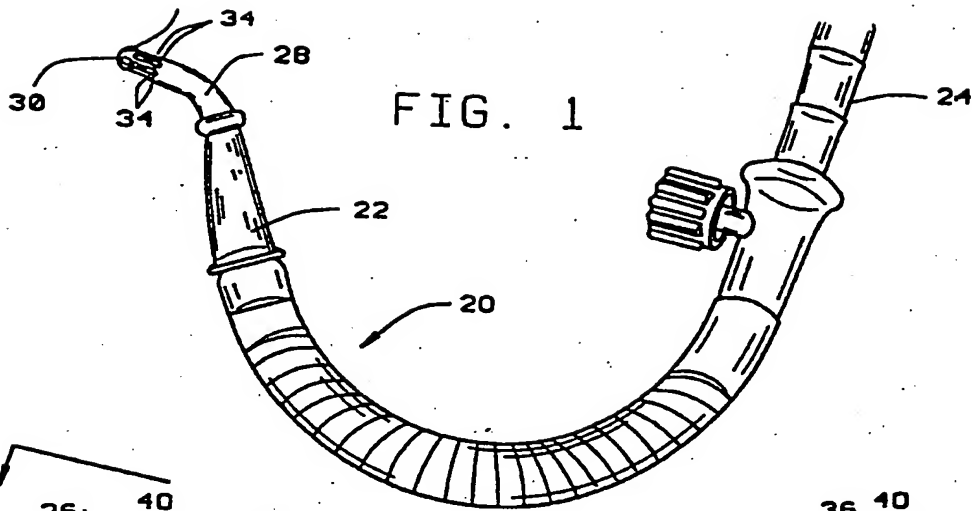
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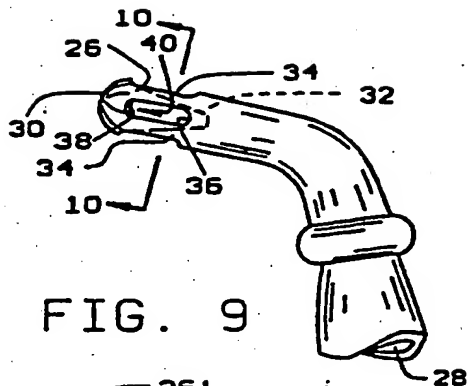


FIG. 9

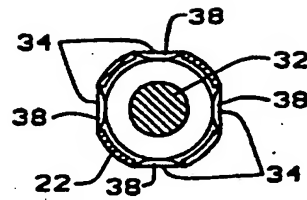


FIG. 10

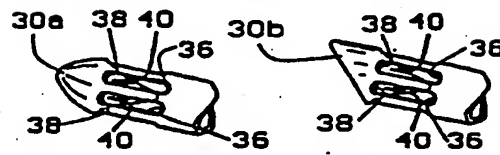


FIG. 11 FIG. 12

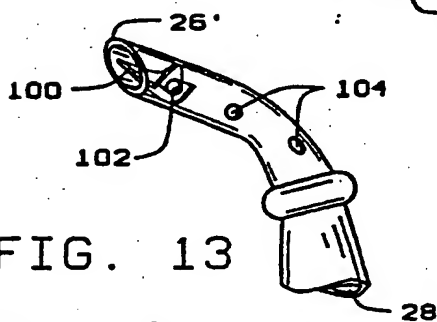


FIG. 13

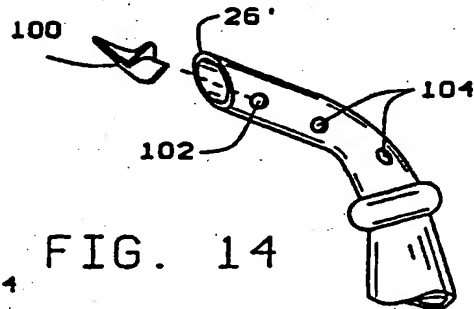


FIG. 14

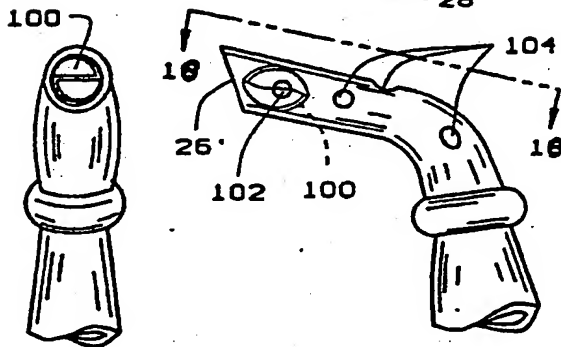


FIG. 15

FIG. 16

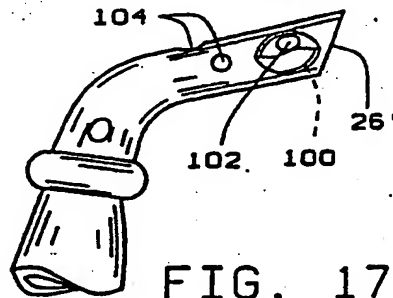


FIG. 17

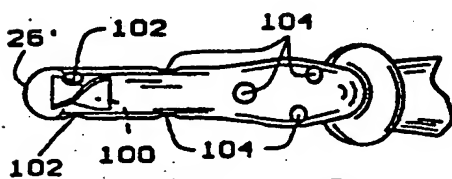


FIG. 18

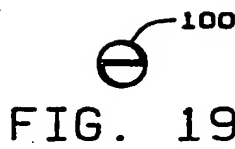


FIG. 19

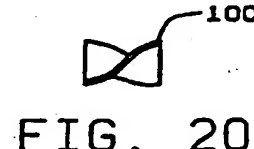


FIG. 20

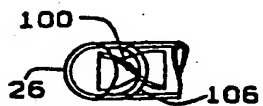


FIG. 21



FIG. 22

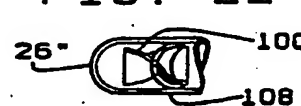


FIG. 23

FIG. 24

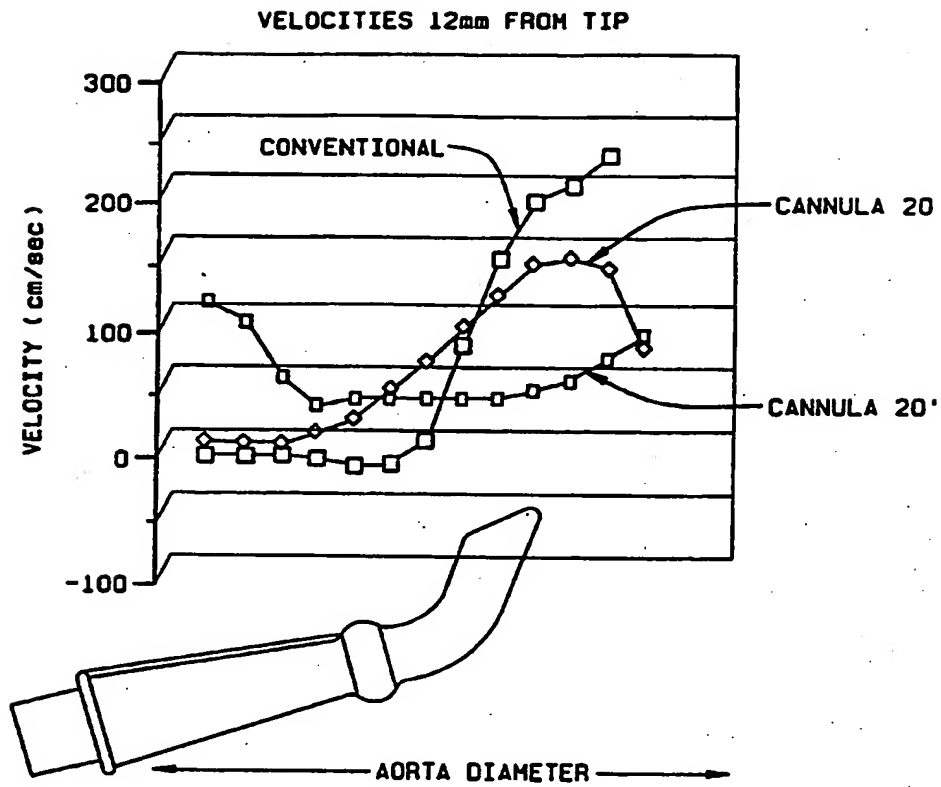


FIG. 26

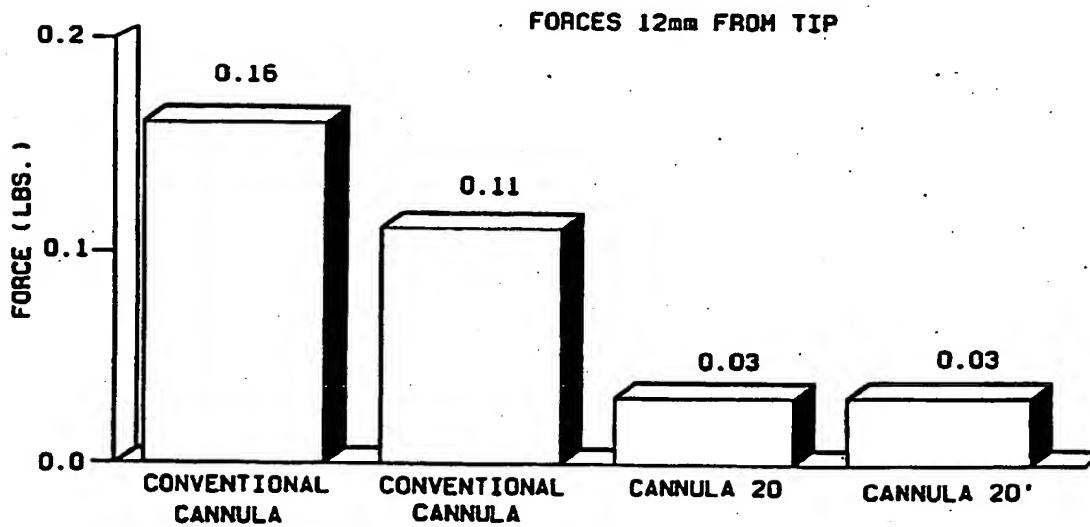


FIG. 27